

REMARKS

Claim Status

New Claims 26 and 27 have been added based on the specification at page 20, lines 13-14.

Claims 11-18 and 20-27 are now pending in the present application.

Title

The Title of the application has been amended to more appropriately reflect the subject matter of the claimed invention.

Information Disclosure Statement

With regard to the assertion in the Office Action that the submitted International Search Report ("ISR") is not a published document, Applicants respectfully point out that the ISR was published as a part of the published PCT application related to the present US application (WO 03/028776 A1). In any event, it appears that the references cited in the ISR have been considered by the Examiner.

Rejection Under 35 U.S.C. §112

Claims 11-18 and 20-25 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to distinctly claim the invention. Applicants respectfully traverse this rejection. The Office Action asserts that the terms "from about", "at least about", and "less than about" are not defined in the claim and the specification does not provide a standard for ascertaining the requisite degree and one skilled in the art would not be reasonably apprised of the scope of the invention. Applicants point out that such claim terms are commonly used in defining numerical ranges, especially in the chemical arts. Applicants submit that one of ordinary skill in the art would understand the scope of the invention from these claim terms based on the common use of these terms in claim drafting, the nature of chemical inventions, and the specification of the present invention. See MPEP §§2173.05(b)(A) and 2173.05(c)(II). The claim limitations relating to temperature and average droplet size are parameters commonly measured by those of skill in the art. One of skill in the art in making such measurements would recognize the

potential for a certain amount of variability in such measurements and as a result would understand the meaning of the claim language "from about", "at least about" and "less than about" as used in the present claims. Applicants therefore submit that this rejection should be withdrawn.

Rejection Under 35 USC § 103(a)

Claims 11-18 and 20-25 have been rejected under 35 U.S.C. §103(a) as being obvious over Osborne et al. (US 6,716,441) and Lin (US 2002/0115968) in view of Gatto et al. (US 6,793,930). Applicants respectfully traverse this rejection.

Osborne et al. teach compositions for efficient release of active ingredients comprising at least one skin care active, a release agent having an HLB of at least about 3, and a hydrophobic barrier protectant. The composition can be typically applied to the skin using a dispensing means, such as an absorbent article. Osborne et al. disclose a long list of suitable skin care active to be incorporated into its release compositions. Included in this list is niacinamide. With respect to incorporating skin care actives into its release compositions, Osborne et al. disclose the following methods:

The skin care actives are typically incorporated into the substantially oleaginous composition as micronized powder; conventional size particulates are less preferred due to the abrasive effect on the skin. As used herein, the "micronized powder" refers to particles having sizes (mean particle diameter and particle size distribution) that are below the tactile threshold and are essentially nonabrasive to the skin, and the "conventional size particles" refers to particles that are tactilely perceptible and provide the scrubbing and abrasive effects. Moreover, it is more difficult to form uniform and stable suspension using large particles in the substantially oleaginous composition of the present invention. Generally, particles having a mean particle diameter greater than about 75 microns are tactilely perceived; thus, the active particles should preferably have their size reduced prior to being incorporated herein. Particles having a wide range of shapes, surface characteristics, and hardness can be used herein, provided the size requirement is met.

Alternatively, the skin care actives may be solubilized in a small amount of water or water-miscible solvents such as lower alcohols, or glycols in the form of a solution, a

suspension, a dispersion, an emulsion or the like, which is incorporated into the substantially oleaginous composition.

See col. 6, lines 24-46 (emphasis added). Osborne et al. thus teach two alternative methods of incorporating its skin care actives into its release compositions: (1) reduce the particle size of the skin care actives prior to incorporating into its release compositions, or (2) solubilize the skin care actives in a small amount of water or water-miscible solvent. Neither of the methods taught by Osborne et al. encompass or suggest the presently claimed method. Osborne et al. thus fails to teach or suggest premixing niacinamide with a material selected from the group consisting of glycerin, propylene glycol, panthenol, and mixtures thereof to form a premix, mixing the premix with a carrier system at a temperature of at least about 35°C, and then milling the premix into a carrier system at a temperature of at least about 35°C until the average droplet diameter of the dispersed premix is less than about 100 microns.

Lin is cited for teaching chitosan in an absorbing article, such as a diaper, for skin care. Lin does not disclose or suggest a lotion comprising niacinamide. Lin therefore does not disclose or suggest premixing niacinamide with a material selected from the group consisting of glycerin, propylene glycol, panthenol, and mixtures thereof to form a premix, mixing the premix with a carrier system at a temperature of at least about 35°C, and then milling the premix into a carrier system at a temperature of at least about 35°C until the average droplet diameter of the dispersed premix is less than about 100 microns. Lin further does not disclose or suggest combining a chitosan material with niacinamide in a solvent and with a carrier system under the process conditions as presently claimed.

Gatto et al. do not teach or suggest a lotion comprising niacinamide. Gatto et al. therefore do not disclose or suggest premixing niacinamide with a material selected from the group consisting of glycerin, propylene glycol, panthenol, and mixtures thereof to form a premix, mixing the premix with a carrier system at a temperature of at least about 35°C, and then milling the premix into a carrier system at a temperature of at least about 35°C until the average droplet diameter of the dispersed premix is less than about 100 microns.

With regard to particle size of its skin care ingredients, Gatto et al. teach that:

Where the ingredients are insoluble in the composition, the average particle size of the ingredients plays an important role in suspending the particles in the composition without substantial agglomeration, stratification and/or settling. The particles should be substantially free of excessively large agglomerates, i.e., there is negligible amount of particles larger than 1000 microns. The average particle size of the skin care ingredients should preferably be less than about 1000 microns, more preferably less than about 100 microns, and most preferably less than about 50 microns.

See col. 11, lines 31-40 (emphasis added). Gatto et al. thus teach that for skin care ingredients that are insoluble in its compositions, such as zinc oxide, the average particle size of the skin care ingredients should be less than about 1000 microns to avoid substantial agglomeration, stratification and/or settling. Gatto et al. thus do not teach or suggest appropriate particle size ranges for skin care ingredients that are not insoluble.

Niacinamide is not typically considered to be an insoluble material, especially in comparison to a material such as zinc oxide utilized by Gatto et al. In the present invention, niacinamide is somewhat soluble in the carrier system of the present lotion at elevated temperatures (e.g. at least about 35°C) and less soluble in the carrier system at ambient temperature. Niacinamide thus tends to crystallize in the carrier system upon cooling to ambient temperature. This crystallization can lead to problems such as instability of the lotion composition or clogging of manufacturing equipment when applying the lotion to substrates such as absorbent articles. However, premixing the niacinamide with a material selected from the group consisting of glycerin, propylene glycol, panthenol, and mixtures thereof to form a premix, mixing the premix with a carrier system at a temperature of at least about 35°C, and then milling the premix into a carrier system at a temperature of at least about 35°C until the average droplet diameter of the dispersed premix is less than about 100 microns tends to minimize the formation of niacinamide crystals in the lotion at ambient temperature. This results in a lotion composition that is stable, readily processable on commercial systems for application to absorbent articles without clogging, and has improved aesthetics. The presently claimed method and its resultant benefits are not taught or suggested in the cited references and thus Applicants submit that the presently claimed invention is not obvious over the cited references.

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Applicants therefore submit that the cited references do not, alone or in combination, render obvious the presently claimed invention. As such, Applicants submit that Claims 11-18 and 20-27 are patentable under 35 U.S.C. §103(a) over Osborne et al. and Lin in view of Gatto et al.

Obviousness-Type Double Patenting Rejection

Claims 11-18 and 20-25 have been provisionally rejected under the doctrine of obviousness-type double patenting as being unpatentable over Claims 1-22 of US Application Serial No. 10/992,383. Once patentable subject matter has been otherwise identified, Applicants will consider submitting any necessary Terminal Disclaimers to obviate any remaining obviousness-type double patenting rejections.

Conclusion

This response represents an earnest effort to place the present application in proper form and to distinguish the invention as claimed from the applied references. In view of the foregoing, entry of the amendments presented herein, reconsideration of this application, and allowance of the pending claims are respectfully requested.

Respectfully submitted,

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